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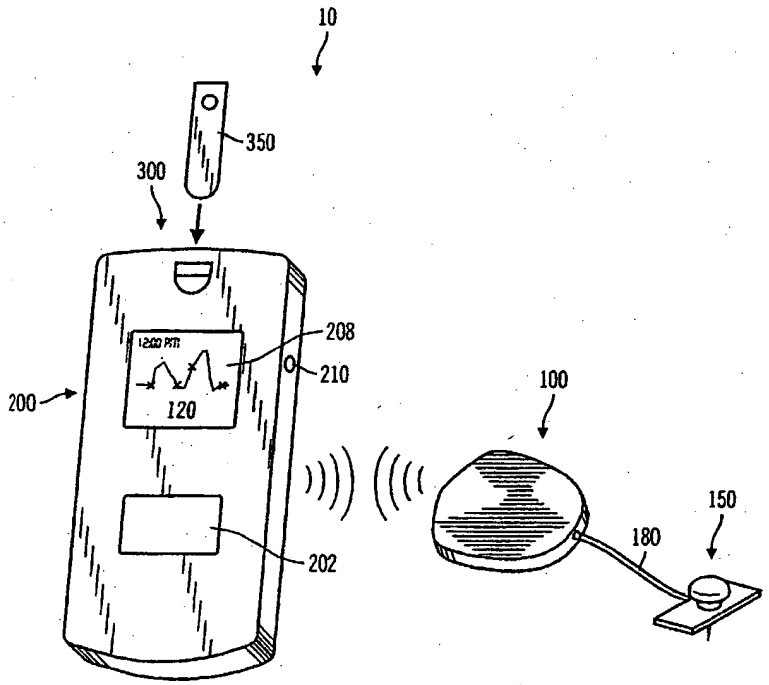

(57) Abstract: A characteristic monitor for use in a system with at least one characteristic sensor that produces a signal indicative of a characteristic of a user includes a housing, a test strip receptacle, a sensor receiver and a processor. The test strip receptacle is for receiving and testing a test strip exposed to an analyte to determine the quantity of the analyte. The sensor receiver is used to receive sensor data signals produced from the at least one characteristic sensor. The processor is coupled to the receiver and the test strip receptacle to process the determined quantity of the analyte and the sensor data signal from the at least one characteristic sensor. The characteristic monitor may further include a transmitter coupled to the processor for transmitting the processed signals to another data receiving device. Preferably, the transmitter transmits the processed signals by radio frequencies. The characteristic monitor may also include a display to show the determined quantity of the analyte and the processed signals from the characteristic sensor. In addition, the characteristic monitor can include a memory to store the determined quantity of the analyte from the test strip receptacle and the processed sensor data signals from the at least one characteristic sensor. Also, the sensor data signals can be received by the sensor receiver continuously, near continuously, and/or intermittently.

WO 00/78210 A1

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CHARACTERISTIC MONITOR SYSTEM FOR USE WITH ANALYTE SENSOR

FIELD OF THE INVENTION

This invention relates to characteristic monitors for use with sensor devices and, in particular embodiments, to characteristic monitors that include a characteristic meter to facilitate testing and monitoring of a patient's condition with coordination between continuous measurements and discrete measurements from a test strip, or the like.

BACKGROUND OF THE INVENTION

Over the years, bodily characteristics have been determined by obtaining a sample of bodily fluid. For example, diabetics often test for blood glucose levels with a blood glucose meter. Traditional blood glucose determinations have utilized a painful finger stick using a lancet to withdraw a small blood sample that is used by the blood glucose meter. This results in discomfort from the lancet as it contacts nerves in the subcutaneous tissue. To obtain a measure of control or information on a diabetic's condition, several finger sticks and tests are required each day (8 or more such tests a day are not uncommon). The pain of lancing and the cumulative discomfort from multiple needle sticks is a strong reason why patients fail to comply with a medical testing regimen used to determine a change in characteristic over a period of time. In addition, these blood glucose meters are only designed to provide data at discrete points, and even with multiple tests a day, do not provide continuous data to show the variations in the characteristic between testing times.

A variety of implantable electrochemical sensors for use with monitors have been developed for detecting and/or quantifying specific agents or compositions in a patient's blood. For instance, glucose sensors have been developed for use in obtaining an indication of blood glucose levels in a diabetic patient. Such readings are useful in monitoring and/or adjusting a treatment regimen which typically includes the regular administration of insulin to the

patient. Thus, blood glucose readings from the monitor improve medical therapies with semi-automated medication infusion pumps of the external type, as generally described in U.S. Patent Nos. 4,562,751; 4,678,408; and 4,685,903; or automated implantable medication infusion pumps, as generally described in U.S. Patent No. 4,573,994, which are herein incorporated by reference. Typical thin film sensors are described in commonly assigned U.S. Patent Nos. 5,390,671; 5,391,250; 5,482,473; and 5,586,553 which are incorporated by reference herein. See also U.S. Patent No. 5,299,571. However, the monitors and electrochemical sensors often require calibration using readings obtained from blood glucose meters to augment and adjust for drift over time. Thus, although the monitors and electrochemical sensors provide more accurate trend information, a separate blood glucose meter is still often required.

SUMMARY OF THE DISCLOSURE

It is an object of an embodiment of the present invention to provide an improved characteristic monitor that is combined with a characteristic meter, which obviates for practical purposes, the above mentioned limitations.

According to an embodiment of the invention, a characteristic monitor for use in a system with at least one characteristic sensor that produces a signal indicative of a characteristic of a user includes a housing, a test strip receptacle, a sensor receiver and a processor. The test strip receptacle is for receiving and testing a test strip exposed to an analyte to determine the quantity of the analyte. The sensor receiver is used to receive sensor data signals produced from the at least one characteristic sensor. The processor is coupled to the sensor receiver and the test strip receptacle to process the determined quantity of the analyte and the sensor data signals from the at least one characteristic sensor. Preferably, the processor monitors the sensor data signals from the sensor receiver to determine when the test receptacle is to be used to perform calibration of the sensor data signals. Further embodiments include a transmitter coupled to the processor for transmitting the processed sensor data signals to another data receiving device. Preferably, the transmitter transmits the processed sensor data signals by radio frequencies. Still further embodiments include a display to show the determined

quantity of the analyte from the test strip receptacle and the processed sensor data signals from the at least one characteristic sensor. Additional embodiments include a memory to store the determined quantity of the analyte from the test strip receptacle and the processed sensor data signals from the at least one characteristic sensor. Also, the sensor data signals can be received by the sensor receiver continuously, near continuously, and/or intermittently.

In other embodiments, the processor includes the ability to program other medical devices, and the transmitter transmits the program to the other medical devices. Also, the transmitter transmits through a relay device between the transmitter and a remotely located processing device. In addition, the relay device increases a maximum distance by amplifying the processed sensor data signals from the transmitter to be received by the remotely located processing device, and the relay device enables the remotely located processing device to be located in a different room than the transmitter. Moreover, the relay device can include a telecommunications device, and when the transmitter generates an alarm the telecommunications device transmits the alarm to a remotely located receiving station.

In particular embodiments, the characteristic sensor is remotely located from the characteristic monitor, and the sensor receiver receives the sensor data signals as wireless signals from the remotely located characteristic sensor. In addition, the characteristic monitor can include a data receiver that is coupled to the processor to receive program instructions from other processing devices.

Further embodiments of the present invention are directed to a characteristic monitor for use in a system with at least one characteristic sensor that produces a signal indicative of a characteristic of a user including a housing, a second characteristic determining device, a sensor receiver and processor. The second characteristic determining device within the housing for receiving and testing an analyte to determine the quantity of the analyte independently of the characteristic sensor. The sensor receiver receives sensor data signals produced from the at least one characteristic sensor. The processor is coupled to the sensor receiver and the second characteristic determining device to process the determined quantity of the analyte from the second characteristic determining

device and the sensor data signals from the at least one characteristic sensor. The processor can monitor the sensor data signals from the sensor receiver to determine when the second characteristic device is to be used to perform calibration of the sensor data signals. In some embodiments, the at least one characteristic sensor is remotely located from the characteristic monitor, and the sensor receiver receives the sensor data signals as wireless signals from the remotely located at least one characteristic sensor. In additional embodiments, the characteristic monitor includes a transmitter that is coupled to the processor for transmitting the processed sensor data signals to another data receiving device. The characteristic monitor can include a display to show the determined quantity of the analyte from the second characteristic determining device and the processed sensor data signals from the at least one characteristic sensor. Other embodiments of the characteristic monitor can include a memory to store the determined quantity of the analyte from the second characteristic determining device and the processed sensor data signals from the at least one characteristic sensor. The characteristic monitor can receive the sensor data signals from the sensor receiver continuously, near continuously and/or intermittently.

In particular embodiments, the second characteristic determining device is a second characteristic monitor that utilizes a second characteristic sensor. For instance, the second characteristic monitor and the second characteristic sensor can use a different sensing technology from that used by the characteristic monitor and the at least one characteristic sensor. The second characteristic determining device can determine the quantity of the analyte continuously, near continuously and/or intermittently. In further embodiments, the second characteristic determining device utilizes a discrete sample to determine the quantity of the analyte, and the second characteristic determining device utilizes a test strip to analyze the sample to determine the quantity of the analyte.

Other features and advantages of the invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings which illustrate, by way of example, various features of embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

A detailed description of embodiments of the invention will be made with reference to the accompanying drawings, wherein like numerals designate corresponding parts in the several figures.

Fig. 3 is a perspective view of a characteristic monitor with a characteristic meter in accordance with a second embodiment of the present invention.

Fig. 4 is a perspective view of a characteristic monitor with a characteristic meter for use with a telemetered glucose sensor and an infusion pump in accordance with a third embodiment of the present invention.

Fig. 5 is a simplified block diagram of a telemetered characteristic monitor transmitter and characteristic monitor in accordance with another embodiment of the present invention.

Fig. 6 is a simplified block diagram of a telemetered characteristic monitor transmitter and characteristic monitor system in accordance with still another embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in the drawings for purposes of illustration, the invention is embodied in a characteristic monitor that obtains data from a sensor set that determines body characteristics on a continuous, near continuous or intermittent basis. In preferred embodiments of the present invention, the characteristic monitor includes a characteristic meter for obtaining discrete measurements that can be utilized by the characteristic monitor for calibration and/or data analysis and verification. Particular embodiments of the sensor set and monitor are for determining glucose levels in the blood and/or bodily fluids of the user. However, it will be recognized that further embodiments of the invention may be used to determine the levels of other agents, characteristics or compositions, such as hormones, cholesterol, medication concentrations, viral loads (e.g., HIV), or the like. The characteristic monitor and sensor are primarily adapted for use with subcutaneous human tissue. However, still further embodiments may be placed with other types of tissue, such as muscle, lymph, organ tissue, veins, arteries or

the like, and used in animal tissue. The characteristic meter is primarily adapted for use with test strips that use a blood sample. However, still further embodiments of the characteristic meter may use other testing structures, such as liquid samples placed in a receptacle, or the like, or test strips that use samples from other fluids, such as interstitial fluid, spinal fluid, saliva, urine, tears, sweat, or the like. In still other embodiments, the characteristic meter may be replaced with another characteristic monitor that utilizes a different sensor technology than the first characteristic monitor, with the principal aim being to provide an automatic continuous, near continuous or intermittent comparison reading to calibrate and ascertain the accuracy of the data from the sensor connected to the first characteristic monitor.

Fig 1 illustrates a perspective view of a characteristic monitor system 10, in accordance with a preferred embodiment of the present invention. The characteristic monitor system 10 includes a subcutaneous sensor set 150 (i.e., a sensor portion is implanted in, for example, dermal subdermal, subcutaneous tissues, or the like), a telemetered characteristic monitor transmitter 100 connected to the sensor set 150 through a sensor cable/connector 180, and a characteristic monitor 200 that includes a characteristic meter 300. The subcutaneous sensor set 150 utilizes an electrode-type sensors, as described in more detail in U.S. Patent. No. 5,391,250, entitled "Method Of Fabricating Thin Film Sensors", U.S. Pat. No. 5,482,473, entitled "Flex Circuit Connector", U.S. Patent No. 5,390,671, entitled "Transcutaneous Sensor Insertion Set", U.S. Patent No. 5,568,806, entitled "Transcutaneous Sensor Insertion Set", U.S. Patent No. 5,586,553, entitled "Transcutaneous Sensor Insertion Set", U.S. Patent No. 5,779,655, entitled "Transducer Introducer Assembly" and co-pending U.S. Patent Application Serial No. 08/871,831, entitled "Disposable Sensor Insertion Assembly," all of which are herein incorporated by reference. However, in alternative embodiments, the sensor may use other types of sensors, such as chemical based, optical based, or the like. In further alternative embodiments, the sensors may be of a type that is used on the external surface of the skin or placed just below the skin layer of the user. Preferred embodiments of a surface mounted sensor would utilize interstitial fluid harvested from underneath the

skin.

The telemetered characteristic monitor transmitter 100 generally includes the capability to transmit data. However, in alternative embodiments, the telemetered characteristic monitor transmitter 100 may include a receiver, or the like, to facilitate two-way communication between the sensor set 150 and the characteristic monitor 200. The characteristic monitor 200 utilizes the transmitted data to determine the characteristic reading. Although a telemetered approach that utilizes RF is preferred, other wireless techniques, such as optical, IR, ultrasonic, or the like may be used. In addition, wired connections may be utilized instead of a telemetered transmission of data from the sensor 150 to the characteristic monitor 200 (see Fig. 3).

The characteristic meter 300 utilizes test strips 350, or the like, with a sample obtained from the body of the patient to determine a characteristic (or analyte level) in a user at a discrete point in time. The discrete measurement from the characteristic meter 300 is stored in a memory of the characteristic monitor 200 and may be used to calibrate the characteristic monitor 200 against the test results from the characteristic meter 300, either in real time or using a post calibration in either the characteristic monitor 200 or during later analysis and review once the test results have been downloaded to a separate computer, communication station, or the like. Possible characteristic meters 300 that may be used are produced by Roche Diagnostics, Bayer corporation, Abbott Medisense, Johnson & Johnson, Mercury Diagnostics, Chronimed, or the like.

Fig. 2 illustrates a simplified flow block diagram of the characteristic monitor 200 shown in Fig. 1. As shown in Fig. 2, the characteristic monitor 200 includes the characteristic meter 300 and also interfaces with a sensor set 150. The characteristic monitor 200 includes a key pad 202, a ROM 204, a RAM 206, a display 208, a data Input and Output (I/O) port 210, a sensor monitor 212, a sensor interface 214, a microprocessor 216, and a battery and/or power supply 218. The characteristic meter 300, included in the characteristic monitor 200, includes a characteristic test meter 302 and a test interface 304.

The microprocessor 216 of the characteristic monitor 200 is activated in several different ways. The keypad 202 is coupled directly to the microprocessor

216 and is useable to activate the microprocessor 216 so that the microprocessor 216 is prepared to store relevant information concerning the sensor data, meter readings, event data, or the like. For instance, the microprocessor 216 will store, the time, the date and the analyte level from a test strip 350 or may be used to record an independent event by the user. In addition, the keypad 202 may be used to activate and control the microprocessor 216 to perform analysis, calibration, control the display 208, download stored data and results, upload program instructions, or the like. The microprocessor 216 may also be activated by receiving a specified signal from the sensor interface 214 indicating connection or receipt of data from a sensor 150 and/or by insertion of a test strip 350 into the test interface 304 of the included characteristic meter 300. Once activated, the microprocessor 216 stores data, analyzes signal values, tests results for accuracy, calibrates, downloads data, presents data for review and analysis, provides instructions, warnings and alarms, or the like.

The microprocessor 216 is coupled to a ROM 204 and a RAM 206. In preferred embodiments, the ROM 204 is an EPROM and the RAM 206 is a static RAM; however, other comparable memory storage components such as dynamic RAM, non-static RAM, rewritable ROMs, flash memory, or the like, may be used. Generally, the ROM 204 stores the programs used by the microprocessor 216 to determine various parameters, such as the amount of an analyte corresponding to a received signal value in the sensor monitor 212 signal value, calibration techniques for adjusting the sensor signals from the sensor 150, characteristic meter 300 operation and correspondence of test results with the sensor signal values, the date and the time, and how to report information to the user. The RAM 206 is used by the microprocessor 216 to store information about the sensor signal values and test strip 350 test results for later recall by the user or the doctor. For example, a user or doctor can transcribe the stored information at a later time to determine compliance with the medical regimen or a comparison of analyte value levels to medication administration. This is accomplished by downloading the information to the display 208 and then transcribing all of the stored records at one time as they appear on the display 208. In addition, the RAM 206 may also store updated program instructions and/or patient specific

information.

In preferred embodiments, the microprocessor 216 is coupled to a data input and output (I/O) port 210, and the user can download the stored information to an external computer (not shown), or the like, through the data I/O port 210 for evaluation, analysis, calibration, or the like. Preferably, the data I/O port 210 is capable of transferring data in both directions so that updated program instructions or reminder alarms can be set by the user or doctor. In preferred embodiments, the I/O port 210 uses infrared (IR) technology, such as that shown and described in U.S. Patent No. 5,376,070 entitled "Data Transfer System for an Infusion Pump", or the like, which is herein incorporated by reference. However, in alternative embodiments, the I/O port 210 may use other data transfer technologies such as cables, fiber optics, RF, or the like. In still other embodiments, the data I/O port 210 may include multiple ports to support multiple communication protocols or methods, or may include a universal port capable of transmitting data in several different modes. In preferred embodiments, the stored data may be downloaded to (or new program instructions and data uploaded from) a computer, communication station, or the like. In alternative embodiments, the stored data may be downloaded to (or new program instructions and data uploaded from) an infusion pump, or the like. In preferred embodiments, the characteristic monitor 200 is the approximate size of a conventional glucose meter or smaller. However, in alternative embodiments, the characteristic monitor 200 may be formed in larger sizes, comparable to a TV controller or a pocket calculator, and may include a larger display 208 to facilitate more complicated or easier programming.

The keypad 202 provides the user with the capability to store additional information, set the date and the time, or set alarms to indicate when to take the next test with the characteristic meter 300. The keypad 202 is used in conjunction with the display 208 to access the various modes, alarms, features, or the like, by utilizing methods typically employed to set the parameters on a conventional glucose meter, an infusion pump, or the like. The keypad 202 may also be used to manipulate the stored data in the characteristic monitor 200 and display the data on the on-board display 208.

The characteristic monitor 200 also includes a self contained battery and power supply 218. Preferably, the characteristic monitor 200 uses batteries (not shown) to provide power to the characteristic monitor 200. For example, a plurality of silver oxide batteries, such as two or three, may be used. However, it is understood that different battery chemistries may be used, such as lithium, alkaline or the like, and different numbers of batteries can be used. In preferred embodiments, the batteries have a life in the range of 1 month to 1 year, and provide a low battery warning alarm. Alternative embodiments may provide longer or shorter battery lifetimes, or include a power port or solar cells to permit recharging of rechargeable batteries in the characteristic monitor 200.

The ROM 204 of the characteristic monitor 200 also stores additional programs to operate and control the characteristic meter 300. Moreover, the RAM 206 of the characteristic monitor 200 can stores results obtained from the characteristic meter 300. As shown in Fig. 2, a test strip 350 for holding an analyte sample is inserted into the test interface 302. This activates the characteristic test meter 304 and the microprocessor 216. The characteristic test meter 304 analyzes the characteristics and sends the analysis results to the microprocessor 216, which displays the results on the display 208 and stores the results in the RAM 206 for later review.

The programs for controlling the sensor monitor 212 of the characteristic monitor 200 are also stored in the ROM 204, and sensor data signal values received by the sensor interface 214 from the sensor set 150 are processed by the sensor monitor 212 and the microprocessor 216, and then the results are stored in the RAM 206. The sensor monitor 212 and the sensor interface 214 can be activated by a wired connection to a sensor set 150 that draws power from the characteristic monitor, by receipt of a signal from the telemetered characteristic monitor transmitter 100, or by the keypad 202. Preferred embodiments use a characteristic monitor 200 (in which the system includes a Potentiostat such as sensor monitor 212) to receive the sensor signals from a telemetered characteristic monitor transmitter 100, as shown in U.S. Patent Application Serial No. 60/103,812 entitled "Telemetered Characteristic Monitor System and Method of Using the Same", which is herein incorporated by reference. In alternative

embodiments, the sensor signals may be received on a more infrequent (or periodic) basis from a Holter-type monitor system, as shown in U.S. Patent Application Serial No. 09/246,661 entitled "An Analyte Sensor and Holter-type Monitor System and Method of Using the Same", which is herein incorporated by reference.

Preferred embodiments store the raw received sensor signals values from the sensor monitor 212 and the test results from the characteristic test meter 304 of the characteristic meter in the RAM 206. However, alternative embodiments may also store calibrated and adjusted results in the RAM 206 for downloading, later analysis and review. Further embodiments may only store adjusted results.

Once activated, the sensor interface 214 continuously, intermittently or near continuously receives signals from the sensor set 150 that are representative of an analyte level being monitored in a user. In preferred embodiments, the sensor monitor 212 is used in conjunction with the microprocessor 216 to store, smooth the data and determine a corresponding analyte level from the signals received from the sensor interface 214. The corresponding value may be shown on the display 208. The characteristic monitor 200 may also perform calibration of the sensor signal values using values provided by the characteristic meter 300. The calibration may be performed on a real-time basis and/or backwards recalibrated (e.g., retrospectively). In further embodiments, the microprocessor 216 monitors the sensor signals from the sensor monitor 212 to determine when the characteristic meter 300 should be used to perform tests to be used for calibration of the sensor data signals. For instance, the microprocessor 216 could indicate that the calibration test should be delayed if the sensor data signals from the sensor monitor 212 are changing too rapidly and suggest a calibration reading when the sensor data readings are relatively stable. Also, the characteristic monitor may prompt the user to perform calibration at periodic preset intervals. Alternatively, the characteristic monitor may prompt the user to perform the calibration based upon event-triggered intervals, that are either user input, such as meals, exercise, or the like, or that are trend input, such as large excursions in glucose levels, faulty or interrupted data readings, or the like.

As shown in Figs. 1-4, the characteristic monitor 200 includes a display

208 that is used to display the results of the measurement received from the sensor in the sensor set 150 via a cable and connector 180 attached to the telemetered characteristic monitor transmitter 100, or the like. In preferred embodiments, the display device 208 is an active matrix LCD. However, alternative embodiments may use other display devices, such as simplified LCD, LED, fluorescent element, plasma screen, or the like. The results and information displayed includes, but is not limited to, trending information of the characteristic (e.g., rate of change of glucose), graphs of historical data, average characteristic levels (e.g., glucose), or the like. Alternative embodiments include the ability to scroll through the data. The display 208 may also be used with the keypad 202 on the characteristic monitor 200 to program or update data in the characteristic monitor 200. In addition, the calibrated data using results from the characteristic meter 300 can be displayed to provide a user with updated trend and glucose level data. This may also be used to update and show differences between the newly calibrated (or additional calibration) data and the data as it was prior to the new calibration (or additional calibration).

In other embodiments, if multiple characteristic sensors are used, the individual data for each characteristic sensor may be stored and displayed to show a comparison and an average between the two characteristic sensors.

It is noted that a typical user can have somewhat diminished visual and tactile abilities due to complications from diabetes or other conditions. Thus, the display 208 and keypad 202 are preferably configured and adapted to the needs of a user with diminished visual and tactile abilities. In alternative embodiments, the data, analyte level value, confirmation of information, or the like can be conveyed to the user by audio signals, such as beeps, speech or the like, or vibrations. Still further embodiments may use a touch screen instead of (or in some cases addition to) the keypad 202 to facilitate water proofing and to minimize changes in the characteristic monitor 200 hardware to accommodate improvements or upgrades. Further alternatives may include a microphone (not shown) and related circuitry to allow voice activated control of the infusion device.

Additional embodiments of the present invention may include a vibrator

alarm (or optional indicator such as an L.E.D.) in either, or both, the telemetered characteristic monitor transmitter 100 and the characteristic monitor 200 to provide a tactile (vibration) alarm to the user, such as sensor set 150 malfunction, improper connection, low battery, missed message, bad data, transmitter interference, or the like. The use of a vibration alarm provides additional reminders to an audio alarm, which could be important to someone suffering an acute reaction, or where it is desireable to have non-audio alarms to preserve and conceal the presence of the characteristic monitor system 10.

As shown in Fig. 4, further embodiments of the characteristic monitor 200 may be used with a telemetered characteristic monitor transmitter 100 coupled to a sensor set 150 and an infusion pump 400 connected to an infusion set 450. In this embodiment, the characteristic monitor 200 is also used to program and obtain data from the infusion pump 400, or the like. This further reduces the amount of equipment, the user must have, since the characteristic monitor 200 already includes a characteristic meter 300 that will be required for calibration of the data from the telemetered characteristic monitor transmitter 100. Thus, the characteristic monitor 200 can coordinate the sensor data and meter data with the data from the infusion pump 400, or update the delivery parameters of the infusion pump 400. The characteristic monitor 200 may also be used to update and program the telemetered characteristic monitor transmitter 100, if the transmitter 100 includes a receiver for remote programming, calibration or data receipt. Thus, the user may need only a single device - the characteristic monitor 200 that will receive data from a sensor set 150, perform discrete tests of an analyte with the characteristic meter 300, program and control an infusion pump 400, and operate to download data or upload programming instructions to a computer, communication station, or the like.

As discussed, the characteristic monitor 200 can also be used to store data obtained from the sensor set 150 and then provide it to either an infusion pump 400, computer or the like for analysis. In further embodiments, the characteristic monitor 200 can include a modem, or the like, to transfer data to and from a healthcare professional. Further embodiments, can receive updated programming or instructions via a modem connection. In addition, a relay or repeater 4 may be

used with a telemetered characteristic monitor transmitter 100 and a characteristic monitor 200 to increase the distance that the telemetered characteristic monitor transmitter 100 can be used with the characteristic monitor 200, as shown in Fig. 5. For example, the relay 4 could be used to provide information to parents of children using the telemetered characteristic monitor transmitter 100 and the sensor set 150 from a distance. The information could be used when children are in another room during sleep or doing activities in a location remote from the parents. In further embodiments, the relay 4 can include the capability to sound an alarm. In addition, the relay 4 may be capable of providing data from sensor set 150 and telemetered characteristic monitor transmitter 100 to a remotely located individual via a modem connected to the relay 4 for display on a monitor, pager or the like. In alternative embodiments, the data from the characteristic monitor 200 and sensor set 150 may also be downloaded through a communication station 8 (or alternatively, through a characteristic monitor 200, other data transfer device, or the like) to a remotely located computer 6 such as a PC, lap top, or the like, over communication lines, by modem or wireless connection, as shown in Fig. 6. Also, some embodiments may omit the communication station 8 and use a direct modem or wireless connection to the computer 6. In further alternatives, either the characteristic monitor 200 or the telemetered characteristic monitor transmitter 100 may transmit an alarm to a remotely located device, such as a communication-station, modem or the like to summon help. In addition, further embodiments of the characteristic monitor 200 may include the capability for simultaneous monitoring of multiple sensors. Data transmission may be to other devices or include the capability to receive data or instructions from other medical devices. Preferred embodiments, as shown in Figs. 1 and 4, use wireless RF frequencies; however, alternative embodiments may utilize IR, optical, ultrasonic, audible frequencies or the like. Further embodiments may also use a wired connection, as shown in Fig. 3.

Preferably, the characteristic monitor system 10 combines the characteristic monitor 200 and character meter 300 into a single device, but avoids an actual wired connection to the sensor set 150 by using a telemetered characteristic monitor transmitter 100. By separating the characteristic monitor

system 10 electronics into two separate devices; a telemetered characteristic monitor transmitter 100 (which attaches to the sensor set 150) and a characteristic monitor 200, several advantages are realized. For instance, the user can more easily conceal the presence of the characteristic monitor system 10, since a wire will not be visible (or cumbersome), with clothing. In also makes it is easier to protect the characteristic monitor 200, which can be removed from the user's body during showers, exercise, sleep or the like. In addition, the use of multiple components (e.g., transmitter 100 and characteristic monitor 200 with a characteristic meter) facilitates upgrades or replacements, since one module or the other can be modified or replaced without requiring complete replacement of the characteristic monitor system 10. Further, the use of multiple components can improve the economics of manufacturing, since some components may require replacement on a more frequent basis, sizing requirements may be different for each module, there may be different assembly environment requirements, and modifications can be made without affecting the other components.

While the description above refers to particular embodiments of the present invention, it will be understood that many modifications may be made without departing from the spirit thereof. The accompanying claims are intended to cover such modifications as would fall within the true scope and spirit of the present invention.

The presently disclosed embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims, rather than the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

WHAT IS CLAIMED IS:

1. A characteristic monitor for use in a system with at least one characteristic sensor that produces a signal indicative of a characteristic of a user, the monitor comprising:

a housing;

test strip receptacle for receiving and testing a test strip exposed to an analyte to determine the quantity of the analyte;

a sensor receiver to receive sensor data signals produced from the at least one characteristic sensor; and

a processor coupled to the sensor receiver and the test strip receptacle to process the determined quantity of the analyte from the test strip receptacle and the sensor data signals from the at least one characteristic sensor.

2. The characteristic monitor device according to claim 1, wherein the at least one characteristic sensor is remotely located from the characteristic monitor, and wherein the sensor receiver receives the sensor data signals as wireless signals from the remotely located at least one characteristic sensor.

3. The characteristic monitor device according to claim 1, further including a transmitter coupled to the processor for transmitting the processed sensor data signals to another data receiving device.

4. The characteristic monitor device according to claim 3, wherein the transmitter transmits the processed sensor signals by radio frequencies.

5. The characteristic monitor device according to claim 3, wherein the processor further includes the ability to program other medical devices, and wherein the transmitter transmits a program to the other medical devices.

6. The characteristic monitor device according to claim 3, wherein the transmitter transmits through a relay device between the transmitter and a remotely located processing device.

7. The characteristic monitor device according to claim 6, wherein the relay device increases a maximum distance by amplifying the processed sensor data signals from the transmitter to be received by the remotely located processing device.

8. The characteristic monitor device according to claim 7, wherein the relay device enables the remotely located processing device to be located in a different room than the transmitter.

9. The characteristic monitor device according to claim 6, wherein the relay device includes a telecommunications device, and wherein when the transmitter generates an alarm the telecommunications device transmits the alarm to a remotely located receiving station.

10. The characteristic monitor device according to claim 1, further including a data receiver, and wherein the data receiver receives program instructions from other processing devices.

11. The characteristic monitor device according to claim 1, further including a display to show the determined quantity of the analyte from the test strip receptacle and the processed sensor data signals from the at least one characteristic sensor.

12. The characteristic monitor device according to claim 1, wherein the processor monitors the sensor data signals from the sensor receiver to determine when the test receptacle is to be used to perform calibration of the sensor data signals.

13. The characteristic monitor device according to claim 1, further including a memory to store the determined quantity of the analyte from the test strip receptacle and the processed sensor data signals from the at least one characteristic sensor.

14. The characteristic monitor device according to claim 1, wherein the sensor data signals are received by the sensor receiver continuously.

15. The characteristic monitor device according to claim 1, wherein the sensor data signals are received by the sensor receiver near continuously.

16. The characteristic monitor device according to claim 1, wherein the sensor data signals are received by the sensor receiver intermittently.

17. A characteristic monitor for use in a system with at least one characteristic sensor that produces a signal indicative of a characteristic of a user, the monitor comprising:

a housing;

a second characteristic determining device within the housing for receiving and testing an analyte to determine the quantity of the analyte independently of the at least one characteristic sensor;

a sensor receiver to receive sensor data signals produced from the at least one characteristic sensor; and

a processor coupled to the sensor receiver and the second characteristic determining device to process the determined quantity of the analyte from the second characteristic determining device and the sensor data signals from the at least one characteristic sensor.

18. The characteristic monitor device according to claim 17, wherein the at least one characteristic sensor is remotely located from the characteristic monitor, and wherein the sensor receiver receives the sensor data signals as wireless signals from the remotely located at least one characteristic sensor.

19. The characteristic monitor device according to claim 17, further including a transmitter coupled to the processor for transmitting the processed sensor data signals to another data receiving device.

20. The characteristic monitor device according to claim 17, further including a display to show the determined quantity of the analyte from the second characteristic determining device and the processed sensor data signals from the at least one characteristic sensor.

21. The characteristic monitor device according to claim 17, wherein the processor monitors the sensor data signals from the sensor receiver to determine when the second characteristic determining device is to be used to perform calibration of the sensor data signals.

22. The characteristic monitor device according to claim 17, further including a memory to store the determined quantity of the analyte from the second characteristic determining device and the processed sensor data signals from the at least one characteristic sensor.

23. The characteristic monitor device according to claim 17, wherein the sensor data signals are received by the sensor receiver continuously.

24. The characteristic monitor device according to claim 17, wherein the sensor data signals are received by the sensor receiver near continuously.

25. The characteristic monitor device according to claim 17, wherein the sensor data signals are received by the sensor receiver intermittently.

26. The characteristic monitor device according to claim 17, wherein the second characteristic determining device is a second characteristic monitor that utilizes a second characteristic sensor.

27. The characteristic monitor device according to claim 26, wherein the determined quantity of the analyte from the second characteristic determining device is determined continuously.

28. The characteristic monitor device according to claim 26, wherein the determined quantity of the analyte from the second characteristic determining device is determined near continuously.

29. The characteristic monitor device according to claim 26, wherein the determined quantity of the analyte from the second characteristic determining device is determined intermittently.

30. The characteristic monitor device according to claim 26, wherein the second characteristic monitor and the second characteristic sensor use a different sensing technology from that used by the at least one characteristic monitor and the characteristic sensor.

31. The characteristic monitor device according to claim 17, wherein the second characteristic determining device utilizes a discrete sample to determine the quantity of the analyte.

32. The characteristic monitor device according to claim 31, wherein the second characteristic determining device utilizes a test strip to analyze the sample to determine the quantity of the analyte.

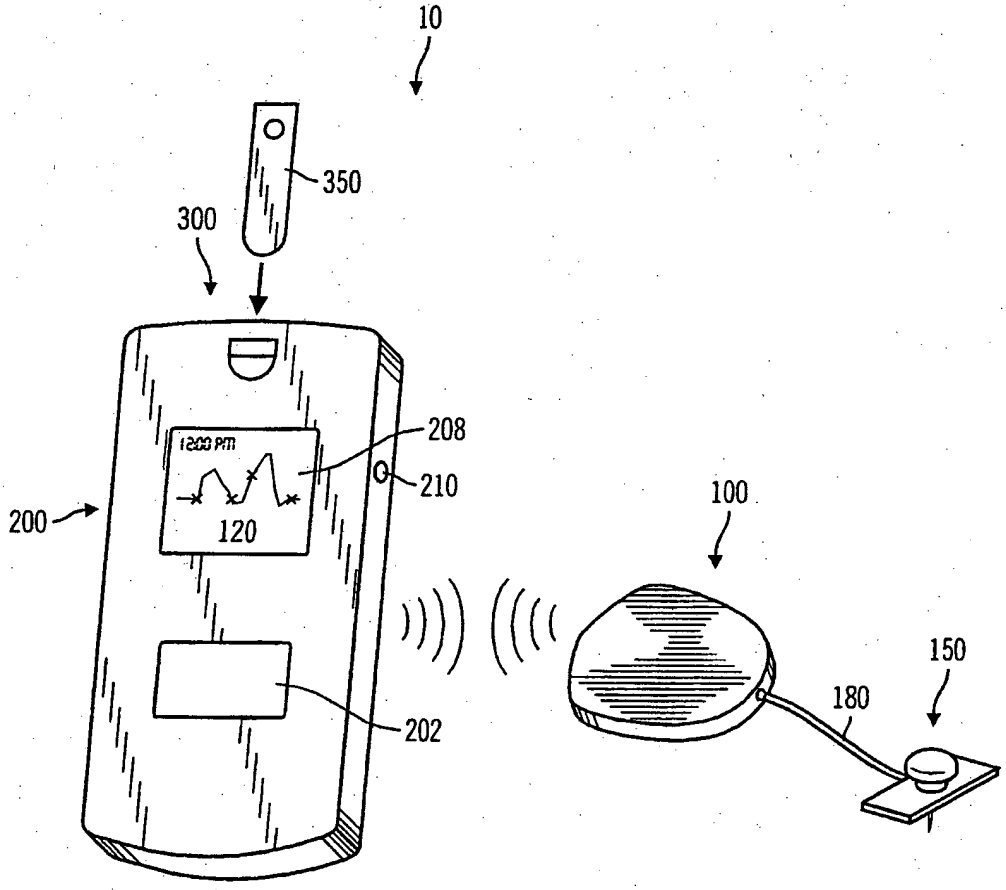

FIG. 1

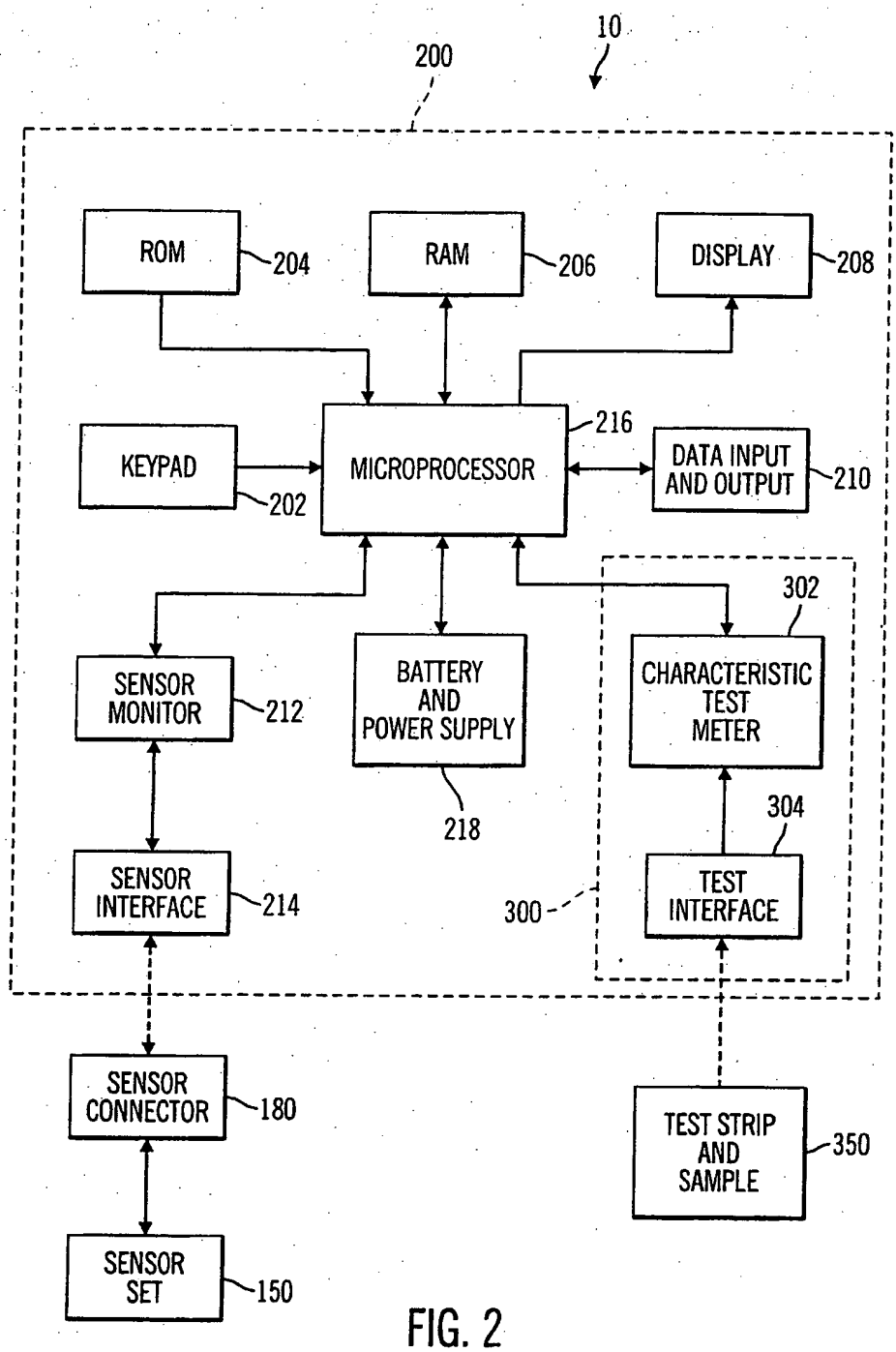
10
200
ROM
204
RAM
206
DISPLAY
208
KEYPAD
202
MICROPROCESSOR
216
DATA INPUT AND OUTPUT
210
302
SENSOR MONITOR
212
BATTERY AND POWER SUPPLY
218
CHARACTERISTIC TEST METER
304
SENSOR INTERFACE
214
300
TEST INTERFACE
SENSOR CONNECTOR
180
TEST STRIP AND SAMPLE
350
SENSOR SET
150

FIG. 2

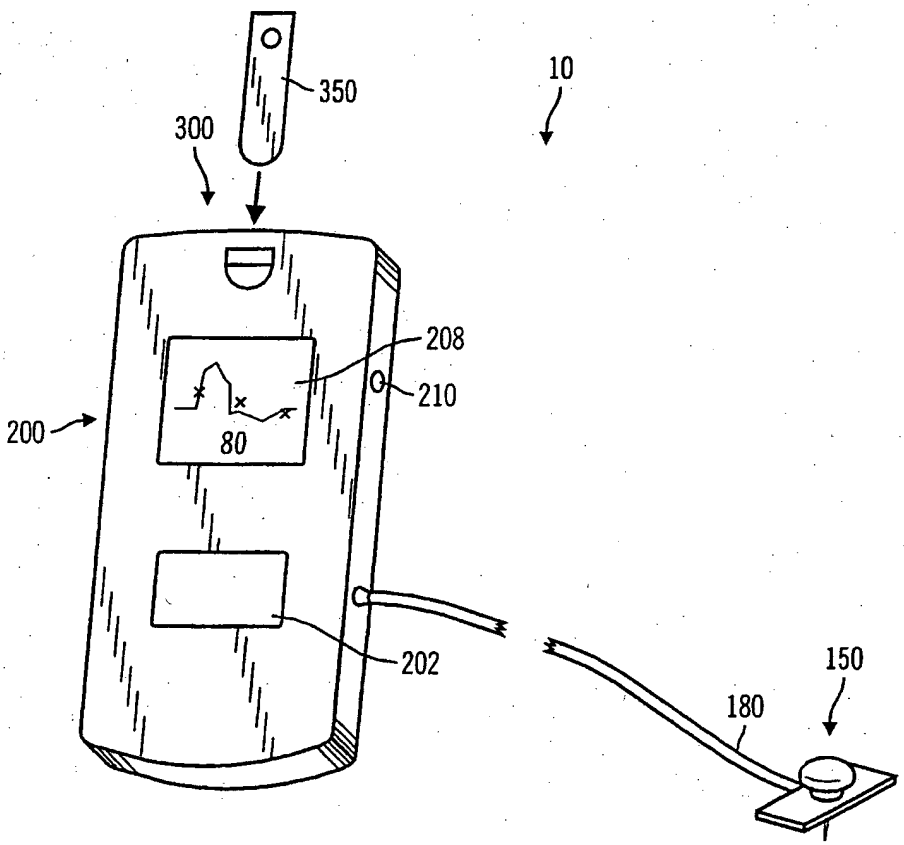

FIG. 3

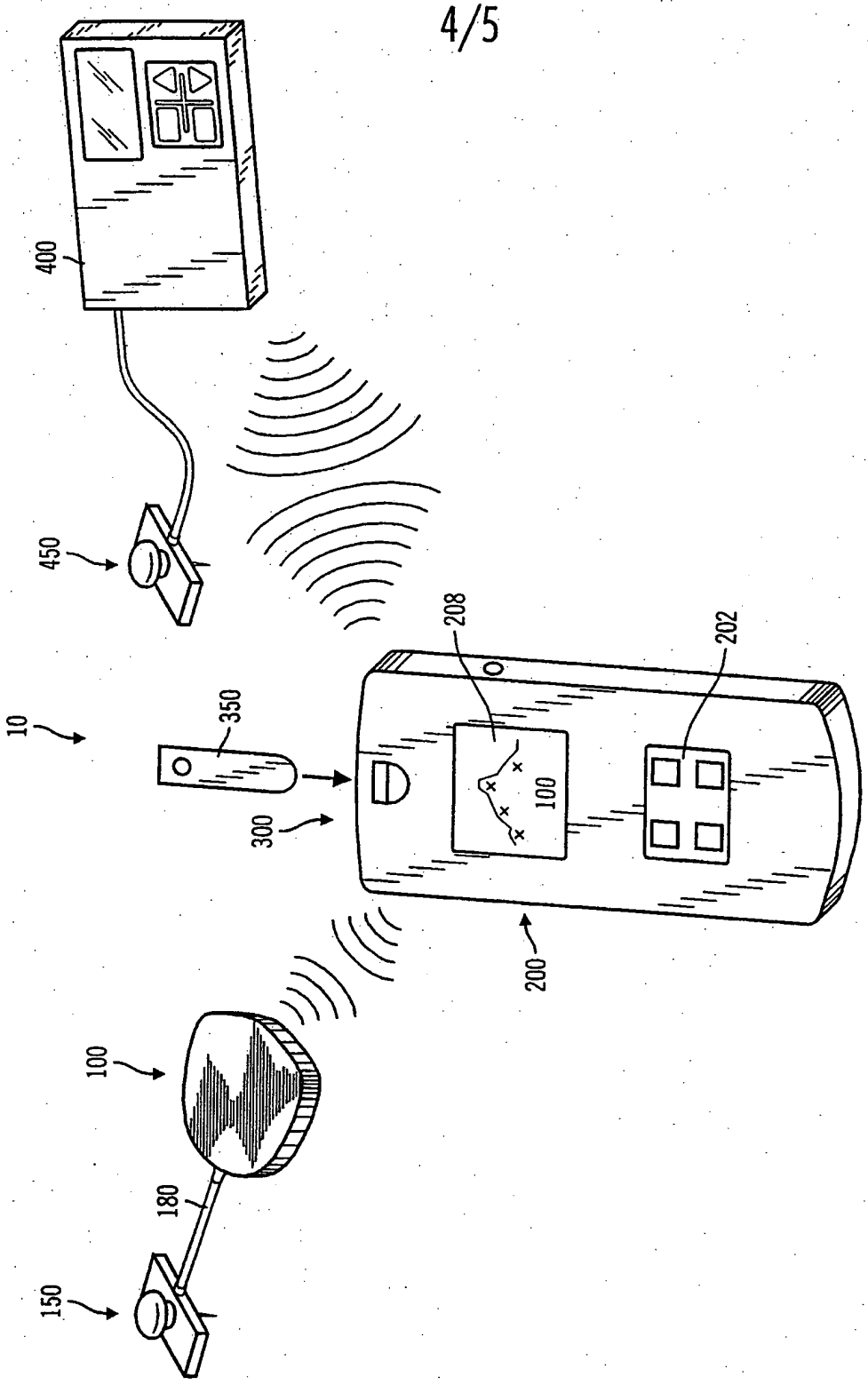

FIG. 4

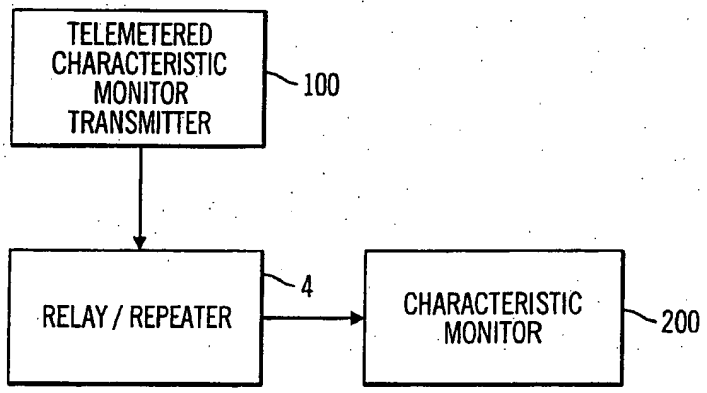
TELEMETERED CHARACTERISTIC MONITOR TRANSMITTER
100
RELAY / REPEATER
4
CHARACTERISTIC MONITOR
200

FIG. 5

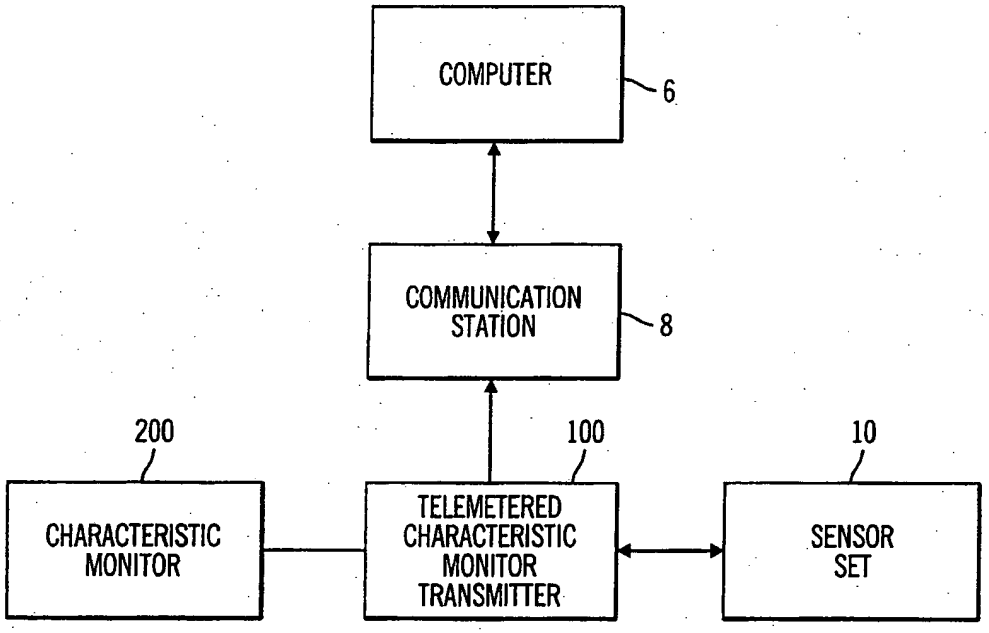
COMPUTER
6
COMMUNICATION STATION
8
200
100
10
CHARACTERISTIC MONITOR
TELEMETERED CHARACTERISTIC MONITOR TRANSMITTER
SENSOR SET

FIG. 6

INTERNATIONAL SEARCH REPORT

Internatl Application No
PCT/US 00/16782

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 507 288 A (BOECKER DIRK ET AL) 16 April 1996 (1996-04-16) the whole document	1,2,11, 13-18, 20, 22-29, 31,32
Y A		3,4,6-8, 10,19 12,21,30
Y	US 5 417 222 A (DEMPSEY MICHAEL K ET AL) 23 May 1995 (1995-05-23) the whole document	3,4,10, 19
Y	EP 0 880 936 A (AKAI KOJI) 2 December 1998 (1998-12-02) the whole document	6-8

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
3 November 2000	15/11/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Chapple, I

1

Form PCT/ISA/210 (second sheet) (July 1992)

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Information on patent family members

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